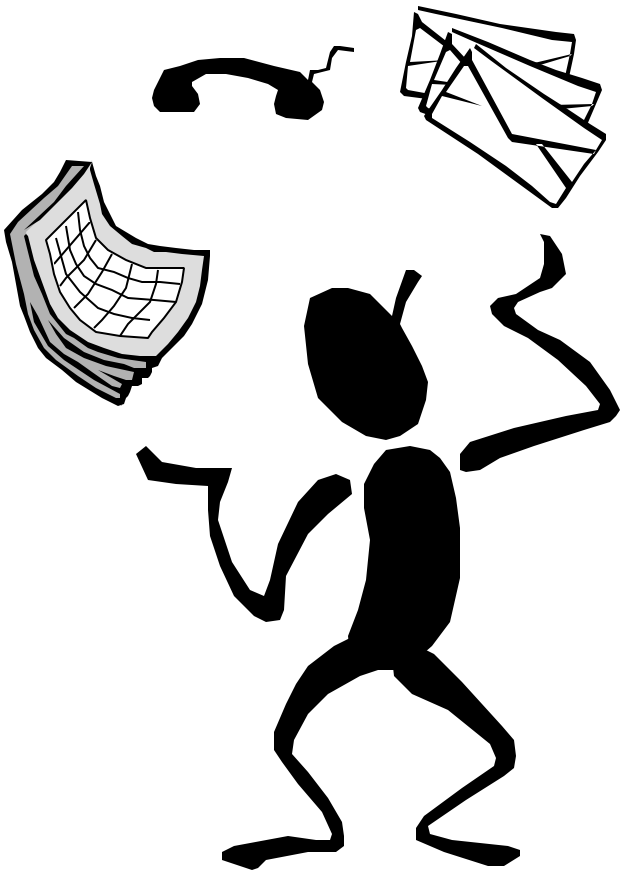
The Reuse of Single-Use Devices

Considerations for FDA While Developing Proposed Strategy

Our Not So Great Juggling Act



- AAMI/FDA meeting
- Develop policy proposal for Center Director and FDA Commissioner
- Promise to “unveil” strategy by October 1999
- Strategy moving through Department as we speak!
- Will be issued via a Notice of Availability and on the FDA Website

Vision for the Future

Current Reality

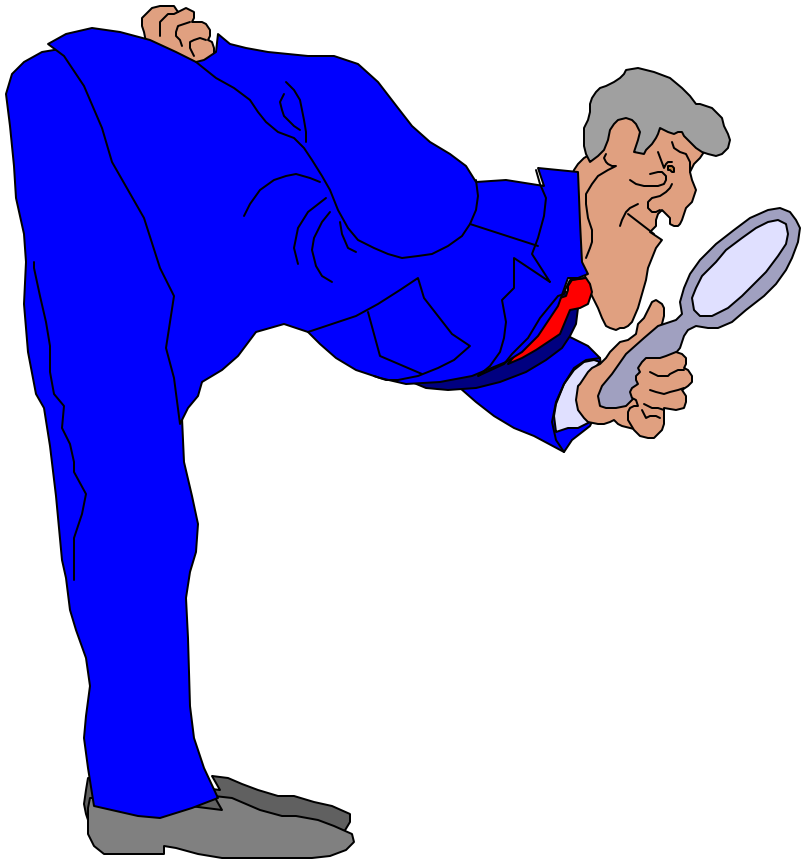
- Widespread practice with little data on safety or effectiveness
- Single use labels not clearly meaningful
- Single use labels don’t identify vulnerabilities
- Patients are not informed - experimentation?

Future Vision

Simple Solutions?

- One voice in the debate suggests calling for identical regulatory controls for reprocessing as for OEMs - call for 510(k)s and PMAs
- An opposing voice suggests we leave General Controls in place as sufficient: Registration and Listing, GMP (Quality System Requirements), Labeling, and Medical Device Reporting
- Neither approach is satisfactory

Why a call for 510(k) won't solve all our problems



- Many devices now reprocessed are 510(k) exempt (Class I and II)
- Submissions would prove problematic to clear from our traditional review process

Why leaving general controls as only regulatory mechanisms doesn't solve all our problems

- Lack of well documented problems does not mean current practice is safe and effective
- Some evidence from FDA and others that reuse presents difficulties

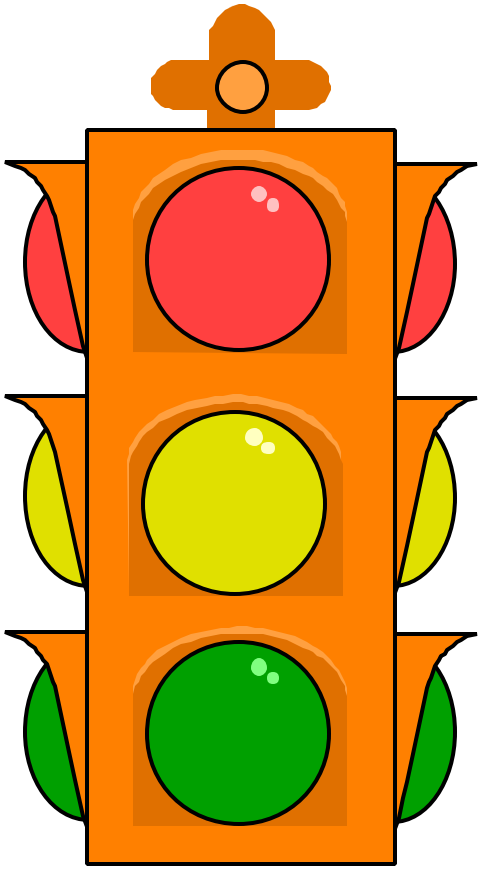
Problems to Solve

- Science base for reuse of a wide variety of products not extensive
- This system inside hospitals and in third parties has grown over time with tacit FDA acceptance
- Reuse is basically a problem of economics and ethics: both are outside of FDA mandate!

Some Guiding Principles

- Capitalize on what we do best: understanding of regulatory control and devices
- Our constraints suggest the importance of partnering/outside leveraging: show leadership but do not solve all by ourselves
- Do not let the perfect serve as the enemy of the good

Regulatory Strategy by Risk



- CDRH recent changes: virtually all programs (from pre through postmarket) are ***risk based***
- Current reprocessing spans a wide range of products
- Recent research suggests that reuse considerations are product specific: need more information on risk and reuse

How do we get there?

- Four committees working rapidly:
  - **Steering**
  - **Policy**
  - **Categorization by risk**
  - **Research**
- Milestones
  - **Strategy paper: October**
  - **Videoconference: Nov. 10**
  - **Public Meeting: Dec. 14**
  - **More detailed guidance than in proposed strategy**
  - **Enforcement**

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Future Vision?

- FDA regulatory approach will be RISK and SCIENCE based
- Leverage outside parties
- Single use labels will have more meaning to users and regulators
- Horizontal and vertical standards have potential

OEMs FDA Reprocessors Hospitals